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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/866,458 | 05/25/2001 | Gary G. Meadows | 618.002US1 | 4123 |

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| EXAMINER |
|---|
| GOLDBERG, JEROME D |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/866,458 | Applicant(s) MEADOWS ET AL. | |
|---|---|---|---|
| | Examiner Jerome D Goldberg | Art Unit 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *5-7 and 21-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 5-7 and 21-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Applicants' remarks about the restriction requirement are noted but the other serotonin agent are classified in different subclasses. The elected fluoxetine is in class 514, subclass 651, while the fluovoxamine is in class 514, subclass 652, paroxetine is in class 514, subclass 652, paroxetine is in class 514, subclass 465, sertraline is in class 514, subclass 657 and citalopran is in class 514, subclass 469. Clearly, more searching would be required for the other serothonin agent. This would be as undue burden on the Examiner. Therefore, the restriction required is seen proper and made Final.

Claims 1-4 and 8-20 are being examined as they read on the elected fluoxetine.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Brandes patent.

The Brandes patent teaches fluoxetine for treating cancer (see col. 19, claims 41 and 40, col. 18, claim 37 and col. 17, claim 23.

The patent teaches that the combination is effective for "cancer such as sarcoma and melanoma" (col. 5, lines 8 and 9) including metastases (col. 12, lines 1-10). The patent does not teach ~~and~~ oral administration but state in col. 4, lines 15-16 that the "antagonist compound employed in the present invention is administered to the patent in any convenient manner...".

Accordingly, one skilled in this art would find ample motivation from the prior art supra to use the claimed fluoxetine against the instant cancers with a reasonable expectation that said composition would be effective. The claims are directed to "comprising" which would include other ingredients. Claims directed to "consisting of" would overcome this rejection.

Claims 1-4, 8-10, 13-16, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific serotonin agent disclosed, does not reasonably provide enablement for the terms "serotonin agent" or "serotonin reuptake inhibitor". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term " a serotonin agent" in

claims 1-4, 8, 13-15, 19 and 20 and "serotonin reuptake inhibitor" in claims 9, 10, and 16 lacks clear exemplary support in the specification as filed. The limited number of examples will not support such a broad terms.

Claims 1, 2, 8-14 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific cancer disclosed, does not reasonably provide enablement for the term "cancer" or "tumor growth". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "cancer" is claims 1, 8-14 and 16-18 and "tumor growth" in claim 2 lack clear exemplary support in the specification as filed.

The cancer therapy art remains highly unpredictable, and no examples exist for efficacy of compound against cancers generally. Therefore, based on the unpredictable nature of the invention and lack of guidance and working examples, and extreme breath of the claims, one skilled in this art could not use the entire scope of the claimed invention without undue experimentation. Changing the term cancers or cancer cells to the specific cancers disclosed would overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Goldberg whose telephone number is 308-4606. The examiner can normally be reached on Monday to Thursday from 9 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone

number for the organization where this application or proceeding is assigned is 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Goldberg/LR

February 20, 2002

JEROME D. GOLDBERG
PRIMARY EXAMINER